

Motus GI Receives FDA Clearance to Market Pure-Vu® GEN2

– FDA clearance marks key regulatory milestone and advances commercial strategy for launch in U.S. hospital market in 2019 –

FORT LAUDERDALE, Fla.--(BUSINESS WIRE)-- [Motus GI Holdings, Inc.](#), (NASDAQ: MOTS) ("Motus GI" or the "Company"), a medical technology company dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for the second-generation [Pure-Vu® System](#) ("Pure-Vu® GEN2") to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure.

This press release features multimedia. View the full release here:
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"Inadequate bowel preparation prior to colonoscopy remains an unmet need that affects a significant percentage of patients' ability to receive a complete and high-quality exam. This often leads to canceled, delayed and aborted procedures, resulting in prolonged hospitalizations and increased costs for both patients and providers," commented Jason B. Samarasena, MD FACG, Associate Clinical Professor of Medicine, Division of Gastroenterology School of Medicine, University of California Irvine. "The Pure-Vu® System provides an important solution to address the significant clinical challenges and inefficiencies associated with inadequate prep and the Pure-Vu® GEN2 provides an innovative, easy to use platform that enables a streamlined approach to the overall procedure."

The Pure-Vu® System is a U.S. FDA-cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard and slim colonoscopes to enable safe and rapid cleansing during the procedure while preserving established procedural workflow and techniques. Pure-Vu® GEN2 has been designed to improve the mobility, setup logistics of the system and enhance navigation through the colon, while retaining all the same cleansing functionality as the first generation of the Pure-Vu® System.

"Receiving FDA clearance for our Pure-Vu® GEN2 represents a major milestone for the Company. The Pure-Vu® System continues to demonstrate outstanding cleansing performance in poorly prepped colons, including the statistically significant improvement in

Pure-Vu® GEN2 System (Photo: Business Wire)

colon cleanliness in hospitalized patients as recently demonstrated by the positive outcome of our REDUCE study. With our robust portfolio of health economic and clinical data coupled with 510(k) clearance from the FDA of Pure-Vu® GEN2, we are now well positioned to execute our planned commercial launch of the Pure-Vu® System this year and advance toward our goal of establishing the Pure-Vu® System as a new standard of care in key endoscopy segments," commented [Tim Moran, Chief Executive Officer of Motus GI](#).

Our planned initial launch will focus on the inpatient colonoscopy market where challenges with insufficient bowel prep slow diagnosis, diminish the quality of care, and add significant costs to hospital systems. Motus GI believes that the Pure-Vu® System may improve quality of care and potentially reduce healthcare costs by reliably and predictably moving patients through the hospital system to a successful examination.

About Motus GI and the Pure-Vu® System

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy. The Company's flagship product is

the Pure-Vu® System, a U.S. FDA cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard and slim colonoscopes to enable safe and rapid cleansing during the procedure while preserving established procedural workflow and techniques. The Pure-Vu® System has received CE mark approval in Europe. The Pure-Vu® System is currently being introduced on a pilot basis in the U.S. market, and the Company is planning to initiate a commercial launch focused on the U.S. hospital market in 2019. Challenges with bowel preparation for inpatient colonoscopy represent a significant area of unmet need that directly affects clinical outcomes and increases the cost of care in a market segment that comprises approximately 1.5 million annual procedures in the U.S. and approximately 4 million annual procedures worldwide. Motus GI believes the Pure-Vu® System may improve outcomes and lower costs for hospitals by reducing the time to successful colonoscopy, minimizing delayed and incomplete procedures, and improving the quality of an exam. In clinical studies to date, the Pure-Vu® System significantly increased the number of patients with an adequate cleansing level, according to the Boston Bowel Preparation Scale Score, a validated assessment instrument.

For more information, visit www.motusgi.com and connect with the Company on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Forward-Looking Statements

This press release contains certain forward-looking statements. Forward-looking statements are based on the Company's current expectations and assumptions. The Private Securities Litigation Reform Act of 1995 provides a safe-harbor for forward-looking statements. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms, including without limitation, risks inherent in the development and commercialization of potential products, uncertainty in the timing and results of clinical trials or regulatory approvals, maintenance of intellectual property rights or other risks discussed in the Company's Form 10-K filed on March 26, 2019, and its other filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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